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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,261

10/02/2003

Mehboob Hussain

HUSSAINIA

5622

1444

7590

03/21/2006

BROWDY AND NEIMARK, P.L.L.C.

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,261

Applicant(s)

HUSSAIN, MEHBOOB

Examiner

Leon Lankford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3 and 4, drawn to an isolated population of bone marrow cells, classified in class 435, subclass 372.
- II. Claim 2, drawn to an isolated population of human bone marrow cells, classified in class 435, subclass 366.
- III. Claims 5-14, drawn to a method of treating a diabetic condition, classified in class 424, subclass 93.7.
- IV. Claim 15, drawn to a method for stimulating the mobilization and differentiation of bone marrow derived cells, classified in class 435, subclass 377.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct inventions and thus are subject to restriction. The inventions are distinct in that the products are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the different subpopulations of bone marrow cells each have individual characteristics that are not shared by the other population; thus the subpopulations are considered distinct and independent. Specifically, the cells in the subpopulation of invention I are CD45⁻, Lin⁻, and Sca⁺; alternatively the cells in the subpopulation of invention II must be human bone marrow cells.

Inventions III and IV are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the methods have distinct methodologies and different effects and are thus considered independent and distinct. Specifically, the

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method of invention III is intended for the treatment of diabetes, and requires administration of bone marrow cells to a patient, such is not required in the method of invention IV. The method of invention IV, rather, is an in vitro method for stimulating the mobilization and differentiation of bone marrow derived cells into pancreatic islet cells and requires a step of treating the bone marrow cells with G-CSF and/or GM-CSF, such is not required in the method of invention III.

Inventions I and II are related to inventions III and IV as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case either of the cell populations of inventions I or II can be used in either of the methods of inventions III or IV; therefore, none of the inventions are so intrinsically linked.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Additionally, upon the election of group III, the following election of species is required:

Claim 9 is generic to the following disclosed patentably distinct species: a) pancreatic diabetes; b) extrapancreatic/endocrine diabetes; c) drug-induced diabetes; d) lipoatropic diabetes; e) myotonic dystrophy-associated diabetes; f) diabetes induced by disturbance of insulin receptors.

The species are independent or distinct because none is rendered obvious by the others in its group and because the disclosure does not connect them by any design, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the

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species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

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patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai*, *In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



LEON B. LANKFORD, JR.
PRIMARY EXAMINER